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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/765,336

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Iontcho R. Vlahov

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BARNES & THORNBURG LLP  
11 SOUTH MERIDIAN  
INDIANAPOLIS, IN 46204

EXAMINER

JONES, DAMERON LEVEST

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/765,336	<b>Applicant(s)</b> VLAHOV ET AL.	
	<b>Examiner</b> D. L. Jones	<b>Art Unit</b> 1618	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 5/2/05; 10/13/06; 10/15/07; & 12/13/07.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-51 and 53-67 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 49-51 and 57-65 is/are allowed.
- 6) ☒ Claim(s) 1,66 and 67 is/are rejected.
- 7) ☒ Claim(s) 2-48 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> .                                  | 6) <input type="checkbox"/> Other: _____                          |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :5/2/05; 10/13/06; 10/15/07; & 12/13/07.

## **ACKNOWLEDGMENTS**

1. The Examiner acknowledges receipt of the amendment filed 12/13/07 wherein claim 11 and 49 were amended; claims 52-56 were canceled; and claims 66 and 67 were added.

**Note:** Claims 1-51 and 53-67 are pending.

## **RESPONSE TO APPLICANT'S AMENDMENTS/ARGUMENTS**

2. The Applicant's arguments and/or amendment filed 12/13/07 to the rejection of the claims made by the Examiner under 35 USC 102, 103, 112, and/or double patenting have been fully considered and deemed persuasive for the reasons set forth below. Therefore, the said rejections are hereby withdrawn.

### **Double Patenting Rejection**

The double patenting rejection is WITHDRAWN for reasons of record in Applicant's response.

### **112 Second Paragraph Rejections**

The 112, second paragraph, rejections are WITHDRAWN for reasons of record in Applicant's response.

### **102 Rejections**

The 102 rejection is WITHDRAWN for reasons of record in Applicant's response.

### **103 Rejections**

I. The 103(a) rejection over Summerton et al is WITHDRAWN because of the unexpected results.

II. The 103(a) rejection over Chari et al is WITHDRAWN for reasons of record in Applicant's response.

## **NEW GROUNDS OF REJECTIONS**

### **112 First Paragraph Rejections**

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Independent claim 1 encompasses delivery conjugates listed in claims 66 and 67 which Applicant is excluding from the conjugates of claim 1 in claims 66 and 67. Thus, critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

In particular, the conjugates being excluded in claims 67 and 68 are encompassed in claim 1. Thus, if it is Applicant's intention to exclude the conjugates, they should be excluded in independent claim 1.

### **112 Second Paragraph Rejections**

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 66 and 67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims as written are ambiguous because they depend on independent claim 1 which is directed to a vitamin drug delivery conjugate that includes the delivery drug conjugates being excluded in claims 66 and 67. Thus, if it is Applicant's intention that the claims exclude the conjugates of claims 66 and 67, Applicant is respectfully requested to exclude those conjugates in independent claim 1.

### **ALLOWABLE CLAIMS**

7. Claims 49-51 and 57-65 are allowable over the prior art of record.

### **CLAIM OBJECTIONS**

8. Claims 2-48 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### **COMMENTS/NOTES**

9. It should be noted that the restriction requirement has been withdrawn and the full scope of the claims searched.

10. It should be noted that no prior art has been cited against the instant invention. However, Applicant's MUST address and overcome the 112 rejections above. In particular, the claims are distinguished over the prior art of record because the prior art neither anticipates nor renders obvious the conjugate, use of the conjugates, or methods of making the conjugates or their intermediates as set forth in the instant invention.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. L. Jones/

D. L. Jones  
Primary Examiner  
Art Unit 1618

March 24, 2008